REMARKS

Claims 1, 3, 4, 33, 35, 36 and 38-40 and 42-44 were pending in the application.

Claim 1 has been rejected as indefinite under 35 U.S.C. Section 112, second paragraph.

Claims 1, 36, 39 40 and 42-44 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Rubenstein (U.S. 7,025,742) in view of Berglund (U.S. 4,416,657) and further in view of Buchwald (U.S. 4,610,658) and Bamberger (U.S. 4,584,994).

Claim 33 has been rejected as being unpatentable as obvious over Rubenstein in view of Berglund, Buchwald and Bamberger and further in view of Burbank (6,193,684).

Claim 35 has been rejected as being unpatentable over Rubenstein in view of Berglund, Buchwald and Bamberger and further in view of Gorsuch (U.S. 5,980,478).

Claims 3, 4 and 38 have been rejected as being unpatentable over Rubenstein in view of Berglund, Buchwald and Bamberger and further in view of Treu (U.S. 6,254,567).

With this response, claims 1, 3, 33, 35, 36, 38-40 and 42-44 are amended and claim 4 is canceled.

Interview Summary

The undersigned thanks the Examiner for the telephonic interview conducted on March 31, 2010. During that interview, applicant's representative explained that one of ordinary skill in the art would not have looked to the prior art relating to cerebrospinal fluid ("CSF") drainage systems, such as Rubenstein, to treat ascites, and indicated that a Declaration supporting the same would be submitted. Additionally, applicant's representative discussed that one of ordinary skill in the art would not have combined Rubenstein and Berglund because Berglund teaches peritoneal drainage without any mechanism to prevent backflow of urine into the peritoneal cavity. While no agreement was reached on allowability of the pending claims, the Examiner agreed to consider expert testimony on the points discussed during the interview.

Amendments to the Pending Claims

With this amendment, applicant has significantly narrowed the scope of the pending claims to more closely correspond to the embodiments depicted in FIGS. 14 and 15 of the pending application. The claims now more closely correspond to the embodiment of the assignee's device currently undergoing preliminary clinical trials. Accordingly, sole independent claim 1 has been amended to recite that the system comprises an implantable pump including "an electromechanical motor and an integrated controller", first and second pressure sensors disposed in fluid communication, respectively, with the first and second tubes and operatively coupled to the controller, and "wherein the integrated controller is programmed to activate the electromechanical motor to pump fluid from the peritoneal cavity to the bladder responsive to the first pressure sensor detecting a pressure in the peritoneal cavity exceeding a first predetermined threshold and the second sensor detecting a pressure in the bladder lower than a second predetermined threshold." Support for these recitations is provided in FIGS. 11, 14 and 15 and paragraphs [0059] and [0065] of the published application. No new matter is added by the amendments.

In addition, claim 1 has been amended to add the word "inlet", thereby obviating the indefiniteness rejection under 35 U.S.C. Section 112, second paragraph.

The § 103 Rejections

Applicant has carefully considered the rejections based on combinations of Rubenstein, Berglund, Buchwald, Bamberger, Burbank, Gorsuch, and Treu and, to the extent rejections based on those combinations are not mooted by the claim amendments set forth herein, traverses those rejections.

For the reasons set forth in the accompanying Declaration of Bruce A. Runyon, a leading expert in the treatment of ascites, applicant respectfully submits that one of ordinary skill in the art would not have been motivated to combine the CSF system of Rubenstein or the penile prosthesis of Bamberger with Berglund or Buchwald. As explained by Dr. Runyon, neither Rubenstein nor Bamberger constitute analogous prior art, while the Berglund device could result in uncontrolled backflow, and there would have been no motivation to combine Buchwald with the other prior art of record. Likewise, one of ordinary skill would not have looked to the peritoneal dialysis system of Treu for an implantable fluid management system because that

system is fully external to the patient. Applicant respectfully submits when the prior art is viewed in context, as explained by Dr. Runyon, one of ordinary skill would have had no motivation or basis to combine any of these disparate references.

Rubenstein

Rubenstein discloses a system for treating dementia in Alzheimer's patients by draining a portion of a patient's cerebrospinal fluid ("CSF") into a body cavity, e.g., the peritoneal cavity. Col. 5, lines 41-54. The system includes a catheter and an implantable pump attached to the catheter, Col. 7, lines 6-19, wherein an inlet of the catheter is positioned within the patient's subarachnoid space in the brain and an outlet is positioned in the peritoneal cavity. Col. 5, lines 1-7 and 41-48. The apparatus includes a power source for the pump, e.g., a battery, and the pump may be remotely operated. Col. 7, lines 11-15. The exterior of the catheter includes a pressure transducer for sensing CSF pressure and sending a signal to a valve within the pump in response to sensing a signal below a threshold value. Col. 7, lines 41-56.

Berglund

Berglund discloses a peritoneal dialysis device which includes implantable catheter 10 portion having fluid passage means 26 leading from proximal end 22 to outlet means 30 that communicates with the patient's peritoneal cavity. Col. 3, lines 33-43. The proximal end is designed to be coupled to an external device to permit inflow of dialysis fluid into the catheter. Distal end 24 of catheter 10 includes domed housing 152, outlet chamber 156 and valve means 32. Col. 5, line 62 to col. 6, line 3. Distal end 24 of catheter 10 lies atop the patient's bladder, with seat 152 of valve means 32 coupled directly coupled to the bladder. See FIG. 2 and col. 6, lines 4-8. Valve means 32, which is manually operated via a direct mechanical linkage, is provided for controlling the flow of fluid between the peritoneal cavity and the patient's bladder. Col. 3, lines 46-50 and col. 6, lines 9-19. The outlet means includes flexible band 122 that slides in canal 120 to either permit or block flow of fluid from the peritoneal cavity to the bladder. Col. 5, lines 44-52. Band 122 includes portion 168 having opening 170, which may be brought into alignment with openings 166 and 167 to permit fluid to pass into the bladder. Col. 6, lines 10-16. Movement of band 122 is accomplished manually by inserting activation device 300 into the bore of the catheter, and rotating lever 314 to cause to slide band 122 to align with openings 166 and 167, so that the exhausted dialysis fluid flows from the peritoneal cavity to the bladder. See col. 7, lines 44-59.

Buchwald

Buchwald discloses a magnetically-coupled pump having a reciprocating (FIG. 1) or rotary (FIG. 8) drive system. Buchwald's rotary drive system of FIG. 8 is axially coupled to an external drive unit. Col. 7, lines 11-18. In particular, Buchwald refers to U.S. Patent No. 3,608,088 to Dorman as providing an exemplary embodiment of a suitable rotary magnetic drive, in which an external drive unit sits atop of an implantable unit with the patient's skin sandwiched in between the implantable and external units. Col. 7, lines 27-34. Buchwald describes that the external portion of the drive system may include a sensor to determine when to cease actuating the implanted portion of the pump. Col. 7, lines 28-34.

Bamberger

Bamberger discloses a penile prosthesis that includes a pair of inflatable cylinders implanted in the penis, a reservoir implanted in the abdomen, and a pump assembly implanted in the scrotum. The pump assembly has an electric motor rotor designed to rotate a rotor when exposed to an AC electromagnetic field of an external stator. Col. 2, lines 14-21. When the rotor rotates, it draws liquid from the reservoir and pumps it into the inflatable cylinders, thereby causing the penis to become erect. Col. 3, lines 34-56.

Treu

Treu discloses a peritoneal dialysis system 10 disposed outside a patient's body that accesses the patient's peritoneal cavity 20 using an access device 18. Col. 4, lines 11-16. The system 10 includes a cycler 14 which interacts with a flow set 12 to pump dialysis solution into and out of the patient's peritoneal cavity 20, and a controller 16 to govern the interaction between the flow set 12 and the cycler 14. Col. 4, lines 17-23. The cycler 14 includes two pressure sensors 76 and 78 to monitor fluid in the inlet and outlet tubes respectively. The controller 16 analyzes the sensed pressures and regulates the pump to maintain a predetermined pressure differential and flow rate. Col. 6, lines 33-41.

* * *

In view of the foregoing teachings of Rubenstein, discussed above, applicant respectfully submits that one of ordinary skill would not have considered using Rubenstein's CSF system for treating ascites. As acknowledged in the Office action, Rubenstein does not teach or suggest a "shunt [that] transfers fluid from the peritoneal cavity to the bladder" or "a system [that] comprises pressure sensors at both ends of the shunt." Office action, pages 3 and 8. Moreover,

as Dr. Runyon explains in his declaration, one of ordinary skill in the art would not have modified the system of Rubenstein or combined that system with the other cited prior art to arrive at the system of amended claim 1 because excess CSF fluid and ascites are not analogous afflictions. Instead, each has a very different source, poses different health risks that raise different concerns, operates on a different time scale and conventionally has been treated by very different systems and methods.

As explained by Dr. Runyon, the fluids are issue in excess CSF and ascites differ in protein content and volume, and thus impose different requirements on an implantable pump (and the resulting battery life). More importantly, however, CSF and ascites present concerns over very different time frames, such that the cost and complexity required to meet the urgency of short-term pressure fluctuations in the skull are simply absent with ascites – where bi-weekly paracenteses are considered the norm. As explained at paragraphs 15-20 of Dr. Runyon's declaration, one of ordinary skill would not have considered the electromechanical pump, controller and sensors used in Rubenstein's CSF drainage system suitable for use in the ascites context because such cost and complexity would not have been deemed justified in the less urgent context of ascites. Rubenstein monitors intracranial pressure in the skull to minimize the risk of elevated pressure that can promptly lead to permanent injury or death, and to minimize the need for serial surgical interventions in the skull. In contrast, patients suffering from refractory ascites typically will have paracentesis performed on at most a bi-weekly basis, so the risk acute injury or death arising from pressure fluctuations is not simply present for ascites patients. As such, one of ordinary skill in the art would not have looked to Rubenstein, or any other CSF system, as providing relevant guidance on the design of an ascites treatment system, much less one having the elements of amended claim 1.

As further explained by Dr. Runyon based on his experience in the field of ascites treatment, even if one of ordinary skill considered coupling an outflow catheter to the bladder – which was contrary to the clinical experience discussed in paragraph 12 of his declaration – a person of ordinary skill would not have looked to Berglund's complicated distal structure to do so. Berglund discloses a pump-less shunt and does not teach or suggest "an implantable pump" having "an electromechanical motor and an integrated controller, "a first pressure sensor," or "a second pressure sensor" as required by amended claim 1. Moreover, one of ordinary skill in the art would not have combined Berglund with the other cited prior art since, as noted by Dr.

Runyon in paragraphs 23-24 of his declaration, the Berglund shunt presents a risk of having urine backflow from the bladder to the peritoneum, with potentially life-threatening consequences. Accordingly, applicant submits that one of ordinary skill in the art would not have looked to Berglund to teach a shunt that "pump[s] fluid from the peritoneal cavity to the bladder" as required by amended claim 1.

With respect to the rejection of prior claim 1 based on Buchwald, applicant notes that claim 1 has been amended to move the claimed "external control module" to amended claim 3, thereby obviating the rejection based on Buchwald. As explained by Dr. Runyon in paragraphs 21-22 of his declaration, Buchwald does not teach or suggest sensors disposed on the implantable portion of the drive system, much less a controller or sensors that monitor pressure within the peritoneum or bladder to determine activation of an electromechanical motor associated with the implantable pump as required by amended claim 1.

Likewise, the rejection of claim 1 based on Bamberger also has been obviated, since the limitation reciting an "external control module including a recess that accepts the protruding portion of the magnetic drive system . . . circumferentially" has been moved to claim 3. As explained by Dr. Runyon in paragraphs 25-26 of his declaration, Bamberger describes a penile prosthesis that lacks many features, e.g., first and second pressure sensors, controller, etc., of amended claim 1. Thus, as Dr. Runyon concludes, one trying to design an ascites treatment system would not have even consulted the field of penis prostheses.

With respect to the rejections based on Treu, applicant notes that patent describes a peritoneal dialysis system that accesses a patient's peritoneal cavity from an access system. All of the pump, controller, and sensors discussed in Treu are located ***outside*** a patient's body. Treu cannot reasonably construed as "An ***implantable*** fluid management system" having an implantable pump, implantable first and second tubes, and implantable first and second pressure sensors as required by amended claim 1. In addition, Treu does not teach or suggest a system with "a second tube coupled between the outlet and a bladder." Because Treu's structure is significantly different than the structure recited in amended claim 1, one of ordinary skill in the art would not have looked to Treu, as stated in Dr. Runyon's Declaration, in designing an ascites treatment system.

Finally, neither Burbank nor Gorsuch provide teaching or motivation such as would lead one of ordinary skill, in designing a new ascites treatment system, to arrive at amended claim 1.

Accordingly, applicant respectfully submits that neither claim 1, nor any claim depending therefrom, is rendered obvious over any combination of Rubenstein, Berglund, Buchwald, Bamberger, Burbank, Gorsuch, and/or Treu, or any of the other prior art of record.

As further evidence of non-obviousness of the claimed invention, Dr. Runyon explains at paragraphs 30-31 of his Declaration that the preliminary clinical data obtained using the inventive system shows that patients suffering from refractory ascites are experiencing dramatically improved quality-of-life resulting from, for example, reduced need for paracentesis, less fluid in the abdomen, easier eating and breathing, and increased energy.

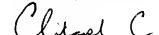
Conclusion

Applicant respectfully submits that in view of the foregoing amendments and remarks, this application patentably distinguishes over the prior art and is in condition for allowance.

A petition fee for a three-month extension of time and a Request for Continued Examination fee will be paid via EFS-Web. No other fees are believed due at this time. However, please charge any required fees, or credit any overpayments, to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

Date: July 2, 2010



61,531

By: Christopher C. Bolten, Esq. (Reg. No.)
For: Nicola A. Pisano, Esq. 34,408
JONES DAY
222 East 41st Street
New York, New York 10017-6702
(858) 314-1200